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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/604,424	07/20/2003	Sarfaraz Niazi	2003-2	1423
27134	7590	11/17/2004	EXAMINER	
SARFARAZ K. NIAZI 20 RIVERSIDE DRIVE DEERFIELD, IL 60015			DAVIS, RUTH A	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/604,424

Applicant(s)

NIAZI ET AL.

Examiner

Ruth A. Davis

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claim Objections

1. Claims 5 and 6 are objected to because of the following informalities:

In claim 5 line 9, the term "itche" should be spelled "itch".

In claim 6 line 4, the term "applicationh" should be spelled "application".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1 – 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and its dependents are drawn to a composition however are rendered vague and indefinite for reciting "QS" in claim 1 line 5. Applicant may prefer to spell out the full term followed by the abbreviation in parenthesis. For purposes of examination, the term "QS" has been interpreted as a quantity sufficient.

In claim 5, line 4 – 5, the phrase "(e.g., poison ivy)" renders the claim indefinite because it is unclear whether the limitation is part of the claimed invention. Specifically, it is unclear if the example of poison ivy is recited as a limitation. See MPEP § 2173.05(d).

Claim 5 is further indefinite for reciting “scratch reaction itch”, “diabetic itch”, and “aging skin itch”, as these terms are not commonly used in the art, and neither the claim language nor specification adequately define these terms.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1 – 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Niazi (US 6419963) and Niazi (US 6555118) in view of Sibley et al. (US 5362488).

Applicant claims a composition for topical treatment of itch in humans and animals, comprising 0.1 – 10% bee propolis, 1 – 10% stearic acid, 1 – 10% *Opuntia Ficus indica*, 1 – 10%

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beta sitosterol, 2 – 20% natural beeswax and vegetable oil in a quantity sufficient to volume.

The propolis and Opuntia are alcoholic extracts; the beta sitosterol and stearic acid are natural or synthetic; and the vegetable oil is olive oil. The composition is used for itch due to scratch reaction, anal, vaginal, scalp, plant, insect, sunburn, chemical, eczema, pruritis dermatitis, dibetic itch, ageing skin, athlete's foot, chickenpox, jock itch, hives, healing burns, wounds, dry winter itch, stress related scalp itch; and is in the form of an ointment, cream, lotion, liquid, aerosol, powder, poultice, dressing, spray or other form suitable for topical administration; and contains ingredients suitable for the form.

Niazi '963 teaches a pharmaceutical composition for treating diaper rash and dermatitis (abstract, col.2 line 21-28) comprising 2 – 20% natural beeswax, olive oil, 1 – 50% beta-sitosterol (abstract, col.7 line 40-45) wherein the beeswax may be propolis (col.9 line 43-53). The composition is in a form suitable for topical application such as an ointment, cream, lotion, solution, poultice, spray or bandage (dressing) (claims). Niazi teaches the beeswax propolis is an alcoholic extract (col.9 line 43-53). The composition may also contain naturally derived anti-inflammatory agents and antimicrobial agents (abstract).

Niazi '118 teaches a pharmaceutical composition for treating diaper rash and dermatitis comprising 1 – 20% alcoholic extracts of Opuntia and beta-sitosterol in a vegetable oil-wax base (abstract). Niazi teaches the Opuntia ficus indica is anti-inflammatory (col.6 line 11-22).

The references do not teach a composition comprising the instant ingredients together in a single composition. However, as evidenced by the cited references, each of the claimed ingredients were known in the art to treat diaper rash and dermatitis. At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the instant

ingredients into a single composition for their commonly known and used purpose of treating diaper rash and/or dermatitis. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by the cited references to combine the instant ingredient in the claimed amounts, with a reasonable expectation for successfully obtaining a composition effective to treat diaper rash and/or dermatitis. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518.

The references do not teach the compositions further comprising stearic acid. However, the references do teach the compositions in various forms for topical application, to include ointments and creams (abstract, claims). At the time of the claimed invention, stearic acid was well known and used in diaper rash/dermatitis creams and ointments. In support, Sibley teaches a diaper rash cream comprising 1 – 9% stearic acid (abstract, Tables 1, 2, claims). At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the composition obtained by the combined teachings of Niazi '963 and Niazi '118 with stearic acid, since it was well known and used in such ointments and creams, as evidenced by Sibley. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Niazi '963, Niazi '118 and Sibley to combine the instant ingredients in the claimed amounts with a reasonable expectation for successfully obtaining an effective composition for treating diaper rash and/or dermatitis.

Although the references do not teach the composition for treating itch due to each of the claimed conditions, the intended use of the claimed composition does not patentably distinguish

the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the composition of the prior art. In the instant case, the intended use fails to create a structural difference, thus, the intended use is not limiting. Please note that when applicant claims a composition in terms of function, and the composition of the prior art appears to be the same, the Examiner may make rejections under both 35 U.S.C 102 and 103 (MPEP 2112).

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ruth A. Davis
November 9, 2004
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A handwritten signature in black ink, appearing to read 'Ruth A. Davis', is positioned to the right of the typed name and date.